



USDA Foreign Agricultural Service

GAIN Report

Global Agriculture Information Network

Template Version 2.09

Required Report – Public Distribution

Date: 7/18/2006

GAIN Report Number: UY6003

Uruguay

Biotechnology

Annual

2006

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Report Highlights:

There are three events approved for commercialization in Uruguay: one soybean variety (MON 40-3-2) and two corn varieties (MON 810 and BT11). With the creation of the National Coordination Committee, (CNC) the current government has established a moratorium on GMO approvals until a new biosafety framework is developed.

Includes PSD Changes: No

Includes Trade Matrix: No

Annual Report

Buenos Aires [AR1]

[UY]

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Executive Summary

Uruguay, a relatively small country located between Argentina and Brazil, now ranks 10th among countries in the number of acres planted with biotech varieties.

In 1995 the Government of Uruguay (GOU) formally endorsed the use of biotechnology and took concrete steps towards the oversight and regulation of biotechnology products by creating a risk assessment commission for genetically modified organisms (GMOs). In 2000, per Decree 249/00, with the creation of the Risk Assessment Commission of Genetically Modified Plants (CERV), a regulatory framework was established to authorize the introduction, use and manipulation of GMOs in the country, but under the current administration, a new committee that will be in charge of developing a new regulatory framework was created. One of main objectives of this new approach is to allow more participation of all the interested parties. In the meantime, a de facto moratorium is imposed on the approval of new events until the new framework is finalized. Labeling provisions are still not in place. There is no law or regulation governing the use of labels such as “non GMO” or “biotech free”. In addition, consumer associations, environmental groups and producer associations have a more active role in the approval process, as they are represented in the CNC.

Production

Authorized Biotech events for production and commercialization are:

Soybeans, event 40-3-2 (approved 1996)

Corn, event MON 810 (approved 2003)

Corn, event Bt 11 (approved 2004)

Soybeans

Soybean harvested area, increased from 77,000 HAS. in MY2002/03 to over 300,000 HAS. in MY2005/06. Approximately 99 percent of total soybean area is planted with Round-up Ready soybeans.

Expansion area in Uruguay is not as abundant as it is in Argentina, but Uruguayan producers do have the benefit of not paying a 23.5 percent export tax on production, as their Argentine counterparts must pay.

Corn

Until August 2003, GMOs were only used in soybean production in Uruguay. In 2003, after much uncertainty, the authorization for the importation and commercialization of Monsanto's insect-resistant corn (variety MON 810) was released by the GOU. More recently in 2004, Bt 11 corn was approved, arousing opposition among environmentalists and leftists.

GMO corn (MON 810) was commercially planted in 2003 for the first time. In 2004, Bt 11 maize was approved for production and commercialization.

Evolution of area planted (conventional corn and Bt)

Year	Total Area (has)	Bt Area (has)	Percentage
2003	44,923	1,150	3
2004	60,601	23,300	38
2005	53,400	30,000	56

Rice

Uruguay is traditionally a rice exporter. Thus, the adoption in Uruguay of rice varieties containing biotech events will depend, almost exclusively, on the acceptance of these events in Uruguay's export markets. Rice producers are very open to the idea of biotechnology but they are unlikely to adopt new technologies that may jeopardize their export markets.

However, there is one event under research. Rice lines LLRICE06 and LLRICE62, which are genetically engineered to express tolerance to glufosinate ammonium, the active ingredient in phosphinothricin herbicides, are currently under research in Uruguay.

Other Crops Under Development

In general, approval of new events in Uruguay is linked to approvals granted in Argentina. All studies and research done in the neighboring country are taken into account.

Corn

There are several corn varieties currently under research NK603, NK 603 x MON 810 and Herculex: DAS-01507-1 (TC 1507)

White Clover

Approved for research, this variety, the first forage event under study in Uruguay, was developed in Australia by Professor German Spangenberg, an Uruguayan botanist currently at La Trobe University.

Numerous biotechnology strategies are being considered with respect to the improvement of nutritional quality through altering the biosynthesis of lignin, soluble carbohydrates, and protoantocianinas and the regulated expression of proteins rich in essential amino acids, resistant to rumen. Attempts are also being made to increase resistance to pathogens and pests and to manipulate growth and development in order to increase persistence and delay senescence, impede flowering and negatively regulate pollen allergens.

Policy

Domestically, the GOU has set up guidelines and procedures to oversee and regulate the introduction of biotechnology products into the environment and market. Oversight and regulatory responsibilities are vested in the Risk Assessment Commission of Genetically Modified Plants (CERV), which is headed by the Ministry of Livestock, Agriculture and Fisheries (MGAP.) Member organizations also include the Ministry of Housing, Land Management and the Environment, the Ministry of Public Health, the National Seed Institute; and the National Agricultural Research Institute. The Commission is responsible for considering, on a case-by-case basis, the potential risks and benefits of each new biotech product.

Biosafety regulations were established following the mandate of the Convention of Biological Diversity. At the 1992 Earth Summit in Rio de Janeiro, world leaders agreed on a comprehensive strategy for "sustainable development" -- meeting our needs while ensuring that we leave a healthy and viable world for future generations. One of the key agreements adopted at Rio was the Convention on Biological Diversity. This pact among the vast majority of the world's governments sets out commitments for maintaining the world's ecological underpinnings economic development ensures. The Convention establishes three main goals: the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits from the use of genetic resources. Uruguay (along with Chile and Costa Rica) adapted this existing legislation for seeds and plant health inspection services.

The regulatory procedure, which does not cover laboratory research, includes risk assessment and risk management. It includes consultation with a broad range of specialists and stakeholders (social scientists and representatives of civil society) apart from those usually included (toxicologists, nutritionists, molecular biologists, and plant breeders). However, the final decision on the release of GMOs falls within the scope of both the MGAP and the Ministry of Economics and Finance.

Main duties of the Risk Assessment Commission include:

1. To create the rules to perform the risk assessment for the introduction, use, and manipulation of GMOs and their parts,
2. To analyze case by case, using sound science, the risk inherent in each product,
3. To provide advice to the competent authorities (Ministry of Livestock, Agriculture, and Fisheries, and the Ministry of Economy and Finance) regarding authorizations,
4. To advise the competent authorities about risk management and communication measures to be adopted in each case; and,
5. To advise the Uruguayan Government (GOU) about plant GMO biosafety.

The Risk Assessment Commission will also create working groups for specific tasks when necessary and will request technical advice from universities and public or private research centers, as well as of independent specialists recognized by their technical proficiency.

The commission includes representatives of the following ministries:

1. Ministry of Livestock, Agriculture and Fisheries (this representative occupies the presidency of the Commission),

2. Ministry of Environment (this representative occupies the vicepresidency of the Commission),
3. Ministry of Public Health,
4. National Seed Institute (INASE); and,
5. National Agricultural Research Institute (INIA).

Approvals from Argentina, United States and Canada are taken into account as a precedent in the approval evaluation process.

As anticipated in last year's biotech report (UY5003), the current government has a completely different approach to GMOs, more conservative and stressing the importance of strengthening multi sectorial participation in the evaluation process, in a way to establish a transparent framework. A few months ago, a new committee has been created, the National Coordination Committee (CNC) that will develop a new regulatory framework for GMOs. Approval of new events is suspended until the new framework is developed. The CNC includes representatives of all interested parties in the aspects related to biosecurity (23 organizations are represented), such as NGOs, environmentalists groups and producer associations, among others, that now will be able to voice their concerns, opinions and their analysis of the current approval process.

The National Project will be based on the creation of six sub commissions and the methodology to be used will be based in the identification of strengths, weaknesses, opportunities and threats. The focus is set mainly the integration of new institutional players for the risk analysis and decision process. All sub commissions will interact and work in conjunction in order to gather all relevant information to develop a proposal of a national biosafety framework. Those sub commissions evaluate different areas. Primary objectives are:

- Evaluation of environmental impact,
- Evaluation of effects in human health,
- Evaluation of socioeconomic impact,
- Evaluation of utilization of GMOs,
- Research and development, and
- Cover administrative aspects.

Besides the creation of the CNC, GOU took the first steps towards the formulation of the national biosecurity framework by hiring a private company that is generating a national survey directed to the public in general, producers, and scientists not specialized in the subject. With this information, GOU will have a segmented opinion study that will help monitor the status of knowledge of the population.

The expected timeframe for the conclusion of the National Project for the development of a biosafety framework is approximately 18 months.

Cartagena Biosafety Protocol

Uruguay has yet to ratify the Cartagena Biosafety Protocol to the 1992 Convention on Biological Diversity (CBD). Up until the Protocol's entry into force (September 2003) Uruguay operated within the framework of the GRULAC Group (Group of Latin American and the Caribbean

Countries) in pursuing the implementation of the biosafety principles outlined in the Cartagena Protocol.

Uruguay, a member of the former Miami Group, has strongly concurred with USG positions on biotech at international fora, in the past, and is highly likely to continue to do so.

Traceability and labeling

Related biotechnology issues such as traceability and labeling (T&L) of GMOs are currently the focus of an internal debate that is being carried out at the governmental level.

As to the European Union's T&L regulations, MGAP contacts have told us that traceability would be a difficult issue in Uruguay since there are commercial, not only scientific, issues at play. They believe that since Uruguay is very dependent on the European market as an outlet for its agricultural products, some kind of traceability system will probably be imposed on Uruguay. However, they have repeatedly made it very clear that the GOU would not support the EU in its efforts to force the issue in international fora.

With regard to labeling of biotech products, contacts at the GOU working level indicate that the GOU does not have a clear position on the issue. Reportedly, however, the MGAP's own position is that labeling should be mandatory for products that are substantially different from their original version, and for those products with a lowered safety threshold.

Meanwhile, there are currently several draft bills enforcing the mandatory labeling of products containing genetically modified components.

Stacked genes

No policy. A stack event is considered to be a whole new event, and it must undergo a full review.

Coexistence

No policy. The European Union's norm was used as a base, but adapted to Uruguay.

Refuges

It is mandatory that 10% of the planted area is kept as a refuge. Uruguay is a small country; therefore, the Seed Institute (INASE) visits the producers in person.

Royalties

All seeds pay extended royalties and the seed law makes a provision for the use of seed at the following year. The company requests the producer to sign a contract promising to pay royalties the next year, therefore they sign a contract between parts.

Trade Barriers / Pending legislation

The current government, favors full “end-product” and “process-based” labeling. On several occasions during the past administration the opposition publicly urged the former president to halt the liberalization of transgenic crops, based on the country’s goal of becoming a “natural country” and on the application of the precautionary principle.

Marketing

There is still misunderstanding and misperception about the safety of GMO plants and foods on human health or in the environment. NGOs have opposed the introduction of GMO crop planting and strongly request labeling on GMO products. There is a scattered, albeit unorganized movement against biotechnology, led by NGOs that systematically misinform the population. The opposition is based mainly on the controversy between GMO crops and the concept of “Uruguay Natural” and on the lack of scientific evidence regarding the innocuousness for human health.

Consumer associations raised concerns about possible negative impacts on human health and the environment. They mainly advocate labeling and traceability and local field trials of GMOs prior to approval. They also question the potential for toxicity and allergenicity of biotech products. These NGOs are now represented in the CNC.

There is some resistance in the meat industry to the approval of White Clover. Clover is used in pastures, and for this reason “natural meats” will cease to be reliably “natural” according to their arguments. But the problems for the beef industry won't be as serious as the problems for the dairy industry, because clover is used more often in dairy production. Additionally this is a threat to the sheep industry. More than anything, clover is used to feed sheep exported to Arab countries that want absolutely nothing to do with GMOs.

Uruguayan meat comes from animals that don't consume GMOs, A study prepared by the National Meat Institute (INAC) concludes that based on the existence of control systems for the entry and use of GMOs in Uruguay, the use of pastures of genetically modified origin in animal feed in pasture production systems is considered to be highly unlikely.

There are no relevant, specific studies on the marketing of biotechnology products in the country.

The Uruguayan Seed Chamber has conducted a survey among farmers in reference to the use of Bt corn seed that provided the following conclusions:

- Bt corn has a high penetration level (67% of total area planted),
- Bt seed reaches good performance compared to the conventional seed,
- Total cost of plague control is lower with the utilization of Bt corn,
- 86% of consulted farmers are more satisfied with the plague control with Bt seed than conventional seed,
- 9 out of 10 farmers do not mention any damage related to the use of Bt corn,
- 100% of consulted farmers use refuges,

- 30% of consulted farmers plans to increase the area dedicated to Bt corn, 50% expressed they will maintain the same area, and 18% expressed they will diminish the area, where the reasons voiced are not related to Bt seed, and
- Farmers are even more optimistic when talking about the future of Bt seeds. 86% believe that global area planted will increase in the next 5 years, and 66% of them expressed that they will personally increase the use of Bt seed in that timeframe.

APPENDIX A: Status of Products Approval

Crop	Trait Category	Event/ Applicant	Trait Description	Status
Soybean	Herbicide Tolerant	40-3-2 Monsanto	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Corn	Insect Resistant	MON 810 Monsanto	Resistant European Corn Borer	Approved Feed and/or Food
Corn	Insect and Herbicide Tolerance)	Bt 11 Syngenta Seeds	Resistant European Corn Borer and Glufosinate Ammonium	Approved Feed and/or Food
Corn	Herbicide Tolerance	NK 603 Monsanto	Glyphosate Herbicide Tolerant	Research
Rice	Herbicide Tolerance	LLRice 06 Bayer	Glufosinate resistance	Research
White Clover	Virus Resistance	LXR Phytogene	Alfalfa.Mosaic Virus	Research
Corn	Insect and Herbicide Tolerance	TC 1507 Herculex DowAgro Sciences	Resistant to European Corn Borer and to Glufosinate Ammonium	Research
Corn	Insect Resistance and Herbicide Tolerance	NK603 x MON 810	Glyphosate Tolerance and Resistance to European Corn Borer	Research

APPENDIX B: Relevant Current Laws and Regulations**Law 16.466: Environmental Impact Evaluation Law – 1994**

This law states that it is of general and national interest to protect the environment against any type of degradation, destruction or contamination, as well the prevention of the negative or noxious environmental impacts.

Law 17283: Environmental Protection Law – 2000

Art. 23 Biosafety. The Ministry of Environment will apply the measures needed to prevent and control environmental risks from the creation, manipulation, use or environmental release of GMOs until a competent authority is designated.

Law 9202: Public Health Law – 1934

This law establishes the Ministry of Health as the regulatory organization in all the issues related to public health.

Law 16811: Seed Law: 1997

This law regulates the production, certification and trade of seeds, the National Register of Production Fields and the protection of plant creations.

INASE, among other duties must:

- Control the seed production and trade, overseeing for the compliance of the rules established by the law.
- Control the national registration of cultivars.

Law 3921: Plant Protection Law – 1911

This law prevents the introduction and dissemination of plant pests.

The MAGP is responsible for the development and organization of the plant health protection in Uruguay, and for the administration and supervision of the national system for plant protection and phytosanitary surveillance.

Decree 249/00 - August 2000

The objective of Decree 249/00 is to promote the safe use of biotechnology by creating an adequate level of protection for GMOs, preventing adverse effects on agricultural production and conservation and sustaining biodiversity.

The introduction, use and manipulation of plants and their genetically modified parts, independently from the manner or regime under which this operation is performed, will only be allowed with previous authorization, granted by the competent authorities.

Applications of Decree 249/00

The development of events under contained use.

- Development of tests and field trials under specific biosafety conditions.
- The evaluation of trials according to law 16811
- Seed multiplication
- Initial production or importation (with the intended use of food, feed or processing).

APPENDIX C: Process to Obtain Approval from GOU

The process to obtain approval from GOU involves a formal application (form SOL-OGM- 1) that includes the following data:

- A.** Applicant: name, address and registration number in the general register of seed producers and traders.
- B.** Legal responsible: name and address
- C.** Technical responsible
- D.** Specie:
 - Regular name
 - Botanical name
- E.** Event
- F.** Cultivar, if applicable
- G.** Origin of material
- H.** Proposed use
 - 1. Development of experiments under contained use
 - 2. Development of tests and field trials under protection or under specific Biotech conditions.
 - 3. Evaluation of National Production Cultivars
 - 4. Seed multiplication
 - 5. Production or first time importation with the intended use (food or feed processing)
 - 6. Other:
- I.** Countries where application has been submitted (if any) indicating which states and date of submission
- J.** Countries where authorization has been granted (if any) indicating states and date of approval.

Once the applicant has complied with this request, the risk analysis commission will perform the risk analysis evaluation on the following basis:

- Case by case
- Adherence to sound science
- The impact on the environment, biological diversity and the eventual effects on human, animal, and plant health.
- Compliance with international guidelines.

After the risk analysis evaluation is performed, the Commission will advise the competent authorities about risk management and communication measures.

Before adopting a resolution, the Competent Authority will publish in national newspapers the name of the GMO, name of the applicant, requested use as well as a summary of the risk analysis evaluation. During a 20 days period after publication, the public has the opportunity to voice opposition.

Failure to comply with all conditions of a granted authorization may lead to cancellation of the permit and to legal actions.